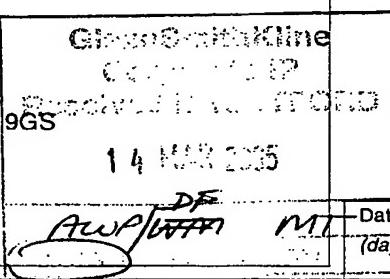


# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

## NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Applicant's or agent's file reference AWP/PG5049	Date of mailing (day/month/year)
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11.03.2005

## IMPORTANT NOTIFICATION

International application No. PCT/EP 03/14550	International filing date (day/month/year) 18.12.2003	Priority date (day/month/year) 20.12.2002
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Applicant GLAXO GROUP LIMITED et al.
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1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/B/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:

  
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Authorized Officer

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**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**  
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference AWP/PG5049	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP 03/14550	International filing date ( <i>day/month/year</i> ) 18.12.2003	Priority date ( <i>day/month/year</i> ) 20.12.2002
International Patent Classification (IPC) or both national classification and IPC B01D11/04		
Applicant GLAXO GROUP LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of sheets.
3. This report contains indications relating to the following items:
- I  Basis of the opinion
  - II  Priority
  - III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV  Lack of unity of invention
  - V  Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI  Certain documents cited
  - VII  Certain defects in the international application
  - VIII  Certain observations on the international application

Date of submission of the demand  11.06.2004	Date of completion of this report  11.03.2005
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Degen, M Telephone No. +49 89 2399-8612



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP 03/14550

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-20 as originally filed

**Claims, Numbers**

1-12 as originally filed

**Drawings, Sheets**

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP 03/14550

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees, the applicant has:

- restricted the claims.
  - paid additional fees.
  - paid additional fees under protest.
  - neither restricted nor paid additional fees.
2.  This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- complied with.
  - not complied with for the following reasons:  
**see separate sheet**
4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:
- all parts.
  - the parts relating to claims Nos. .

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	3,6,7
	No: Claims	1,2,4,5,8-12
Inventive step (IS)	Yes: Claims	6
	No: Claims	3, 7
Industrial applicability (IA)	Yes: Claims	1-12
	No: Claims	

2. Citations and explanations

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/EP 03/14550**

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**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP 03/14550

Reference is made to the following documents mentioned in the international search report (ISR):

- D1: US-A-5 543 057 (WHITING PHILIP ET AL) 6 August 1996 (1996-08-06)
- D2: EP-A-1 005 903 (EBARA CORP) 7 June 2000 (2000-06-07)
- D3: US 2002/179540 A1 (PERRUT MICHEL) 5 December 2002 (2002-12-05)
- D4: US-B-6 440 3371 (HANNA MAZEN ET AL) 27 August 2002 (2002-08-27)
- D5: US-A-5 252 224 (KUHARICH EVAN F ET AL) 12 October 1993 (1993-10-12)
- D6: WO 99/65469 A (RTP PHARMA INC) 23 December 1999 (1999-12-23)

**Re Item IV**

**Lack of unity of invention**

1. This Authority considers that there are three inventions covered by the claims, namely:

- I: Claims 1-4, 11, 12 directed to:
  - a process for the isolation of particles produced by (another) process working at high pressure, wherein said particles are isolated as a suspension in a non-supercritical fluid.
  - Particles isolated from a high pressure process as a suspension in a non-supercritical fluid.
  - An apparatus for the isolation of produced particles as a suspension in a non-supercritical fluid.
- II: Claims 5, 6, 11, 12 directed to:
  - an apparatus and a process for the homogenisation of a particle product, wherein the particles are in a suspension.
  - The particles produced by such a process.
- III: Claims 7-12 directed to:
  - a process for the isolation of a product consisting of more than one component produced by separate high pressure processes.

Due the fact that subject-matter of **claims 1 and 2** is totally disclosed in the documents cited in the international search report (cf. following Item V), the first claimed group of inventions is as such intrinsically not unitary (3 inventions: process/product/apparatus) and not unitary with the other two mentioned groups of inventions:

- the common concept linking together the first group of inventions with the second

- one is the suspension containing the product as produced in a high pressure process. This concept is however known in the art (cf. item V).
- the common concept linking together the first group of inventions with the third one is the product as produced in a high pressure process. This concept is however known in the art (cf. item V).

Thus, neither the combination of the essential features nor the inherent problem to be solved (and consequently also the corresponding solutions thereof) in the group of inventions are so linked as to form a single general inventive concept.

Particularly, there is no technical connection between the solutions of the different technical problems addressed in the three groups of invention which could give the expression to common inventive features.

The application, hence does not meet the requirements of unity of invention as defined in Rules 13.1 and 13.2 PCT.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

The applicant did not restrict but paid additional examination fees. Thus, this opinion covers the complete set of claims.

**1. First Invention (Claims 1-4, 11, 12)**

- 1.1 The subject-matter of **claims 1 and 2** is already known from **D1** (cf. fig. 1; col. 5, line 1 - col. 7, line 15), where the particles produced by a supercritical oxidation reaction are recovered as a suspension in water at subcritical conditions (water slurry). Even starting from other documents (e.g. **D2-D6** (cf. to citations in the ISR)) we conclude that the requirements of Art. 33(2) PCT are not met.
- 1.2 As to **claim 3**, even if apparently none of the documents mentioned in the ISR mention the presence of both a pressure and temperature control, it is believed that it is a standard practice for the skilled man to foresee such controls in order to avoid possible damages of the collection vessel.

For example, in **D1** the supercritic fluid is water ( $T_c=374\text{ }^{\circ}\text{C}$ ,  $P_c=218\text{ bar}$ ). Now, if the collection vessel is in carbon steel material, it is mandatory to limit the fluid temperatures below e.g.  $400\text{ }^{\circ}\text{C}$  using a temperature control. As required by any safety standard, the pressures as well must be controlled. Thus the presence of these two features is not considered to be inventive as the advantages so achieved are straightforward or even standard practice for the skilled man.

- 1.3 As to **claim 4**, the same conclusions as to **claim 2** directly apply. It should be noted, that being this claim redundant to **claim 2** it is not concise (Art. 6 PCT).
  - 1.4 The actual wording of **claim 11** renders its subject-matter unclear as it claims a product but refers back to claims directed to process or apparatus ( in addition to products). Additionally, the wording "as described" or "prepared in a different way" are totally unclear: described where and which different way is meant? Are all different ways suitable for obtaining the product? The requirements of Art. 6 PCT are therefore not met. It should be noted, that **D1** shows the use of powders as a feed.
  - 1.5 Apart the wrong dependency, the wording "facilitates" renders the subject-matter of **claim 12** unclear (Art. 6 PCT) as it does not state which features are responsible for the alleged facilitation. All **D1-D6** show processes that facilitate the formation and isolation of products (Art. 33(2) PCT).
2. **Second Invention ( Claims 5, 6, 11, 12)**
- 2.1 The subject-matter of **claim 5** is anticipated e.g. by **D2** (cf. citations in the ISR) where a slurry is homogenized by a rotating shaft (Art. 33(2) PCT).
  - 2.2 The process of **claim 6** is neither known from nor rendered obvious by any of the cited prior art. Through the step of recycling the homogenized slurry, better product quality can be obtained.
  - 2.3 For **claims 11 and 12** refer to point 1.4 and 1.5 above.
3. **Third invention (Claims 7-12)**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP 03/14550

- 3.1 The subject-matter of **claim 7**, even if not anticipated by the cited prior art does not seem to introduce patentable subject-matter as it appears to merely a combination of two known processes (e.g. those known from D1) without showing, however, any unexpected effect as required by Art. 33(3) PCT.
- 3.2 Products comprising more than one component, for example 2 components and where the second component coats the first are known in the art (e.g. medicaments, bonbons etc.). The subject-matter of **claims 8-10** is not allowable under Art. 33(2) PCT.
- 3.4 For **claims 11 and 12** refer to point 1.4 and 1.5 above.